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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,483	03/13/2001	Dennis W. Goupil	BioCure 190	3748

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,483

Applicant(s)

GOUPIL ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-21-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,8-13 and 39-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8-13 and 39-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of claims and remarks dated 10-21-04 is acknowledged.

Claims 58, 60 and 61 have been canceled. Applicants state that claims 1, 5, 6, 8-13 and 39-50 and 58 are pending. However, claim 58 has been canceled by this amendment and therefore claims 1, 5, 6, 8-13 and 39-50 are pending.

The following rejections of record have been maintained:

Claim Rejections - 35 USC § 102

4. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,863,972 ('972).

'972 discloses crosslinked polyvinyl alcohol (PVA) particles, wherein the PVA is crosslinked with agents such as glutaraldehyde, glyoxal etc., that are capable of forming cross-linked portions with 2 or more carbon atoms between vinyl alcohol molecules (abstract, col. 3, lines 32-47). Instant specification describes that the pendant chains are attached via acetal linkages to the 1,2 or 1,3-hydroxyl groups and that the cross linking carried out by any chemical or other means (instant page 5). Thus, the glutaraldehyde crosslinked PVA of '972 meet the claimed requirement of pendant groups. '972 disclose the particle size of PVA in the range of 63 to 105 microns (example 2). Further, the biodegradable nature is inherent to PVA particles of '972. Therefore, '972 anticipate instant claims.

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5. Claims 1, 5, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Thanoo (J. Pharm. Pharmacol. 1993).

Thanoo discloses crosslinked polyvinyl alcohol (PVA) microspheres, wherein the PVA is crosslinked with agents such as glutaraldehyde (abstract, page 1 and results and discussion). Instant specification describes that the pendant chains are attached via acetal linkages to the 1,2 or 1,3-hydroxyl groups and that the cross linking carried out by any chemical or other means (instant page 5). Thus, the glutaraldehyde crosslinked PVA of Thanoo meet the claimed requirement of pendant groups. Further, the biodegradable nature is inherent to PVA particles of Thanoo. Fig. 5 of Thanoo shows the release of aspirin upto 24 hours. Therefore, Thanoo anticipates instant claims.

6. Claims 1, 5, 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Thanoo (J. Applied Biomaterials. 1991).

Thanoo discloses crosslinked polyvinyl alcohol (PVA) microspheres, wherein the PVA is crosslinked with agents such as glutaraldehyde (abstract, page 1 and results and discussion). Instant specification describes that the pendant chains are attached via acetal linkages to the 1,2 or 1,3-hydroxyl groups and that the cross linking carried out by any chemical or other means (instant page 5). Thus, the glutaraldehyde crosslinked PVA of Thanoo meet the claimed requirement of pendant groups. Further, Thanoo teaches the OPVA microspheres for incorporating radioopaque material such as barium sulfate and furthermore the biodegradable nature is inherent to PVA particles of Thanoo. Therefore, Thanoo anticipates instant claims.

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7. Claims 39-41, 44, 46 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,508,317 to Muller.

Muller discloses crosslinked polymers of PVA, which contain cyclic acetal or ketal groups and the cross linkable polymers such as the polymers having 1,2-diol or 1,3-diol structure (col. 1). The crosslinkable PVA macromer of Muller has the same structure as that of instant claim 41 (col. 2). Further, Muller teaches cross-linking be carried by photocrosslinking or free radical initiated (col. 12). Muller teaches the use of the polymers in the making of contact lenses, eye bandages, membranes for diffusion control etc (col. 9) and teaches the preparation of article by molding (col. 8).

Accordingly, Muller anticipates instant claims.

Claim Rejections - 35 USC § 103

8. Claims 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thanoo (J. Pharm. Pharmacol. or J. Applied Biomaterials) in view of in view of US 6,265,509 to Muller (Muller).

Thanoo (both references) teach crosslinked PVA but fails to teach the specific formula of the macromer of instant claims.

Muller teaches crosslinked polymers of PVA, which contain cyclic acetal or ketal groups and the cross linkable polymers such as the polymers having 1,2-diol or 1,3-diol structure (col. 1). The crosslinkable PVA macromer of Muller has the same structure as that of instant claim 6 (col. 2). Further, Muller teaches cross-linking be carried by

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photocrosslinking or free radical initiated (col. 12). Muller teaches the use of the polymers in the making of contact lenses, eye bandages, membranes for diffusion control etc ((col. 2-5 and col. 14, lines 50-64).

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the PVA polymers having crosslinkable groups such as that described by Muller in preparing crosslinked PVA polymer microspheres of Thanoo because Muller teaches that their crosslinkable PVA polymer is stable, inexpensive and can be subjected substantial purification.

9. Claims 42, 43, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,508,317 to Muller in view of Thanoo (J. Applied Biomaterials).

Muller fails to teach incorporating active agents or contrast agents in the contact lenses or other articles of Muller made of crosslinkable PVA.

Thanoo, discussed above, teaches microspheres crosslinked PVA for delivering contrast agents, which also meet the requirement of an active agent. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the PVA polymers of Muller for incorporating contrast agents or radioopaque agents such as barium sulphate and use them the polymers as radioopaque hydrogels for application such as vascular embolization because Thanoo teaches PVA has many characteristics that makes it suitable for embolization.

Response to Arguments

Applicant's arguments filed 10-21-04 have been fully considered but they are not persuasive.

Claims 1 and 10 anticipated by '972 patent:

Applicants argue that PVA used in '972 does not have "pendant chains which are crosslinkable" as recited in claims 1 and 10, it simply has hydroxyl groups. Applicants argue that glutaraldehyde does not form pendant groups and only acts as a cross-linker to join vinyl alcohol groups and that the reference does not teach using macromers-macromolecular monomers that are crosslinkable. Applicants' arguments are not persuasive because instant claims do not state what the pendant chains constitute. Further, the claims as presented do not exclude the hydroxyl groups on PVA to read on pendant groups. Instant specification does not define pendant chains, other than that it contains groups that can be crosslinked. The polyvinyl alcohol meets the claim requirement and hence the rejection is proper.

Claims 1, 5 and 8-10 anticipated by Thanoo et al (1993) and claims 1, 5,8,10 and 11 anticipated by Thanoo:

It is argued that both the references teach PVA crosslinked with glutaraldehyde but not teach using monomers having pendant cross-linking chains. Applicants' arguments are not persuasive because as explained above, instant claims do not state what the pendant chains constitute. Further, the claims as presented do not exclude the hydroxyl groups on PVA to read on pendant groups. Instant specification does not

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define pendant chains, other than that it contains groups that can be crosslinked. The polyvinyl alcohol meets the claim requirement and hence the rejection is proper.

Claims 39-41, 44, 46, and 48-50 anticipated by '317:

Applicants acknowledged that the macromers of '317 could be used in the instant application. They argue that the crosslinkable groups are crosslinkable via photo cross-linking, photocrosslinking or a photocyclodimerization and that '317 patent does not teach cross linking via "redox initiated free radical polymerization" as recited by the claims. Applicants' arguments are not persuasive because, instant claims are directed to an article and not to a process of preparing the article and accordingly, the process steps in a product claim does not carry patentability weight. Besides, photocrosslinking does include redox initiated free radical polymerization unless shown otherwise (col.11, lines 24-38). Admittedly, '317 patent discloses the claimed article and hence the rejection has been maintained.

Rejection of claims 6, 12 and 13 as obvious over Thanoo (J. Pharm. Pharmacol. or J. Applied Biomaterials) in view of in view of US 6,265,509 to Muller (Muller) and

Rejection of claims 42, 43, 45 and 47 as obvious over the '317 patent in view of Thanoo:

Applicants argue that the moldings of '317 are produced by introducing the prepolymer into a mould, cross linking the polymer and then removing the article from mould, whereas Thanoo reference teaches microspheres formed by polymerization

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PVA with glutaraldehyde and does not teach the use of prepolymer (macromer) to form large shaped articles also has a drawback of glutaraldehyde cross-linking. With respect to the cross-linking, applicants have not shown any unexpected result with the specific cross-linking method argued. However, '509 does teach both cross-linking, in particular, adding a photoinitiator to free radical crosslinking. '509 provide the suggestion to use the PVA polymer of Thanoo to be used for preparing the claimed hydrogel articles. While Thanoo teaches controlled release of drugs from the microparticles of PVA, '509 teaches that the PVA polymers could be employed in preparing the hydrogel articles in different shapes, suggesting a different use for the same polymer. With respect to the argument regarding the teachings of the specific cross linking, examiner has pointed above, that applicants have not established the criticality of the type of cross linking of '317 include redox initiated free radical polymerization unless shown otherwise (col.11, lines 24-38).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615

July 8, 2005


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